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10/642,553	08/14/2003	Wouter Cornelis Puijk	2183-6064US	3138
24247	7590	11/02/2004	EXAMINER	
TRASK BRITT			LUM, LEON YUN BON	
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SALT LAKE CITY, UT 84110			1641	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,553

Applicant(s)

PUIJK ET AL.

Examiner

Leon Y Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040920.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to a micro-array support, classified in class 422, subclass 68.1.
 - II. Claims 7-12, 24-25 drawn to a process for determining binding, classified in class 435, subclass 7.1.
 - III. Claims 13-21, drawn to a process for determining binding, classified in class 435, subclass 7.92.
 - IV. Claims 22-23, drawn to a binding molecule, classified in class 435, subclass 7.8.
 - V. Claim 26, drawn to a process for interfering with or affecting binding to a synthetic molecule, classified in class 436, subclass 86.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II-III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or

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(2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case apparatus as claimed can be used to practice the materially different process of an identifier, wherein apparatus is attached to a device, and the surface areas are arranged in a predetermined pattern that identifies the device.

4. Inventions I and IV are unrelated, independent, and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group I is a micro-array support with a support surface, surface areas, and surface patches, which are limitations that are not in Group IV. Group IV is a binding molecule with a binding site, which is a limitation that is not in Group I.

Therefore, Groups I and IV have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

5. Inventions I and V are unrelated, independent, and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

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different inventions have different modes of operation, different functions, and different effects. Group I is a micro-array support and Group V is a process for interfering with or affecting binding to a synthetic molecule, which does not require the support of Group I.

Therefore, Groups I and V have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

6. Inventions II and III are unrelated, independent, and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group II is a method with the step of detecting binding of the first member molecule with the second member binding molecule, which is not a limitation in Group III. Group III is a method with the step of having a library of spots of the tentative first member binding molecules, which is not a limitation in Group II.

Therefore, Groups II and III have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

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7. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in the materially different process of liquid filtration, wherein the binding molecule is immobilized on a substrate and binds specifically to analytes in a liquid sample as the sample flows past the substrate, thereby purifying the liquid.

8. Inventions II and V are unrelated, independent, and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group II is a method with the step of detecting binding of the first member molecule with the second member binding molecule, which is not a limitation in Group V. Group V is a method with the step of altering the synthetic molecule such that binding to the synthetic molecule is interfered with or affected, which is not a limitation in Group II.

Therefore, Groups II and V have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

9. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in the materially different process of liquid filtration, wherein the binding molecule is immobilized on a substrate and binds specifically to analytes in a liquid sample as the sample flows past the substrate, thereby purifying the liquid.

10. Inventions III and V are unrelated, independent, and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Group III is a method with the step of having a library of spots of the tentative first member binding molecules, which is not a limitation in Group V. Group V is a method with the step of altering the synthetic molecule such that binding to the synthetic molecule is interfered with or affected, which is not a limitation in Group III.

Therefore, Groups III and V have different modes of operation, different functions, and different effects that distinguish them as unrelated, independent, and distinct inventions.

11. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in the materially different process of liquid filtration, wherein the binding molecule is immobilized on a substrate and binds specifically to analytes in a liquid sample as the sample flows past the substrate, thereby purifying the liquid.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

13. During a telephone conversation with Scott Dorland (for Bretton Crockett, Reg. No. 44,632) on 10/13/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-26 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

15. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Patent Office on 16 February 2001. It is noted, however, that applicant has not filed a certified copy of the 01200551.8 application as required by 35 U.S.C. 119(b).

Specification

16. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure

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sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

17. The abstract of the disclosure is objected to because it contains the legal phraseology "thereof" in line 1. Correction is required. See MPEP § 608.01(b).

18. The disclosure is objected to because of the following informalities: The section entitled "BRIEF DESCRIPTION OF THE DRAWINGS" on page 12, does not have a separate description for Figures 4A, 4B, 4C, 4D, 5A, 5B, and 5C, as is required under MPEP § 608.01(g).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

21. In claim 1, lines 1-3, the phrase “for determining binding of a first member molecule within a library of spots of tentative first member binding molecules with a second member binding molecule” is vague and confusing. It is not clear whether the first member molecule binds with the second member binding molecule, or whether the tentative first member binding molecules bind with the second member binding molecule.

22. In claim 1, line 6, the term “materially” is vague and indefinite. The specification does not provide a definition for the term and it is unclear how the instant term limits the embodiment “surface areas” (line 6) with regards to being materially distinct from the “surface patches” (line 6). Is it not clear whether the surface areas contain different materials from the surface patches, or contain the same materials with different properties from the surface patches, or whether the surface areas are distinct from the surface patches in another manner.

23. In claim 5, line 2, the term “library” is vague and indefinite. The specification does not provide a definition for the term and it is unclear whether the instant term refers to multiple binding molecules or whether the instant term refers to a plurality of unique molecules.

Claim Rejections - 35 USC § 102

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24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yoshimura et al (US 5,512,328).

Yoshimura et al reference teaches a micro-array support comprising a support surface having surface areas and surface patches interspersed within the surface areas, wherein the surface areas are materially distinct from the surface patches (claim 1) and wherein the surface patches are hydrophilic and the surface areas are hydrophobic (claim 2), by disclosing a substrate with a seed material film and an oriented material, wherein the substrate and seed material film differ in hydrophilicity, wherein a portion of the seed material film is removed and the oriented material is formed on the removed portion with the same hydrophilicity or hydrophobicity that matches the removed portion (column 7, lines 29-49, especially lines 29-32, 36-37 and 44-47; and Figure 1), wherein the substrate surface is hydrophilic, the thin film is hydrophobic, and the oriented material is a LB film can be deposited on the substrate (column 8, lines 60-65 and Figure 1(c)), wherein the LB film is a film with a hydrophilic portion and a hydrophobic portion (column 3, lines 29-31), and wherein the LB film can be double and multi-layered (Figures 6(d)-(e)). Therefore, the embodiment of Figure

1(d) shows a hydrophilic substrate 11, a hydrophobic seed material film 12 with a removed portion, an oriented material LB film 15 that is made of molecules comprising both hydrophilic and hydrophobic portions that fill the removed portion of the seed material, wherein the circular hydrophilic portion is attached to the substrate 11, and wherein the hydrophobic portion is exposed. Since Figures 6(d)-(e) indicate that the LB film comprises multiple layers and that the multiple layers can be developed with the hydrophilic circular ends attached to the substrate 67 and such that the free end of the LB film is also hydrophilic, a surface is taught wherein a hydrophilic LB film is interspersed in between hydrophobic seed material on a substrate.

26. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Uo et al (US 4,803,154).

In the instant claims Uo et al reference teaches a micro-array support comprising a support surface having surface areas and surface patches interspersed within the surface areas, wherein the surface areas are materially distinct from the surface patches (claim 1) and wherein the surface patches are hydrophilic and the surface areas are hydrophobic (claim2), by disclosing a spot-membrane (column 4, lines 34-37 and Figure 1), wherein the membrane is a hydrophobic polymer sheet with a number of hydrophilic spots (column 3, lines 39-41 and Figure 1).

With regards to claim 3, Uo et al reference teaches that the surface areas consist essentially of hydrophobic polypropylene and the surface patches consist

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essentially of polypropylene and a hydrophilic material, by disclosing that the spot-membrane comprises a hydrophobic polypropylene polymer sheet and that spots on the hydrophobic sheet comprise glutaraldehyde (column 4, lines 6-23, especially lines 6-8 and 21-22), wherein the glutaraldehyde is hydrophilic, as is well known to one of ordinary skill in the art, and provides the hydrophilic spots on the spot-membrane.

With regards to claim 6, Uo et al reference teaches that the micro-array support further comprises a spot density of at least 25 spots per square centimeter, by disclosing that spots are formed in 4 to 32 spots per each membrane in a size of 0.5 to 15 mm in diameter (column 4, lines 41-44).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uo et al (US 4,803,154) in view of Drumheller (US 5,874,165).

Uo et al reference has been disclosed above, but fails to teach that the hydrophilic material comprises polyacrylic acid.

Drumheller reference teaches a support member comprising a hydrophobic polymeric support of polypropylene and 1st and 2nd layers of hydrophilic polyacrylic acid, in order to provide layers of chemically stable hydrophilic polymers to stably immobilize bioactive species (column 10, lines 47-51; column 11, lines 14-19 and 61-66; column 12, lines 1-2; and column 14, lines 51-54), wherein the bioactive species can include antibodies (column 16, line 26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Uo et al, with a support member comprising a hydrophobic polymeric support of polypropylene and 1st and 2nd layers of hydrophilic polyacrylic acid, as taught by Drumheller, in order to provide layers of chemically stable hydrophilic polymers to stably immobilize bioactive species. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including hydrophilic polyacrylic acid, as taught by Drumheller, in the apparatus of Uo et al, since Uo et al teach substrate surfaces that include hydrophilic areas with immobilized antibodies, and the polyacrylic acid layer taught by Drumheller is one type of hydrophilic material that can also immobilize antibodies.

31. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uo et al (US 4,803,154) in view of Rowe et al (Analytical Chemistry, 1999, 71).

Uo et al reference has been disclosed above and additionally teaches tentative first member binding molecules arranged in spatially addressable spots on the support surface, by disclosing that an immuno-active substance is immobilized on the spot-membrane, wherein the substance is an antibody and is in a plurality of spot locations (column 4, lines 24-33 and Figure 1). However, Uo et al reference fails to disclose a library of tentative first member binding molecules.

Rowe et al reference teaches a plurality of unique antibodies on a biosensor surface, in order to simultaneously measure multiple diverse analytes

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on a single substrate (Table 1; Figure 1 and caption; and page 3851, right column, 3rd paragraph, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Uo et al, with a plurality of unique antibodies on a biosensor surface, as taught by Rowe et al, in order to simultaneously measure multiple diverse analytes on a single substrate. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in providing different types of antibodies, as taught by Rowe et al, in the apparatus of Uo et al, since both Rowe et al and Uo et al references teach a plurality of antibody spot locations on a single substrate surface.

Conclusion

32. No claims are allowed.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

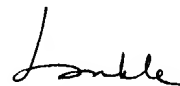
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LYL

Leon Y Lum
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10/28/04